510k: K091777

OCT 20 2009

Alcon®

PREMARKET NOTIFICATION 510(k) SUMMARY

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Director, Regulatory Affairs
Alcon Research, Ltd.
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Device Subject to this 510(k):

Trade Name:	ALCON® UltraChopper
Common Name:	Phacofragmentation tip
Classification Name:	Phacofragmentation tip (per 21 CFR 886.4670)

1. Predicate Devices

The legally marketed devices(s) to which we are claiming equivalence to are:

510(k) Number	Device
K041998	Bausch & Lomb Phaco Chop Needle
K021566	INFINITI® Cataract Extraction System
K063583	ALCON® Vision System (CONSTELLATION®)

2. Device Description

The ALCON® UltraChopper tip is a modified ultrasonic tip that will be added to the existing ALCON® Phaco tip family. The ALCON® UltraChopper tip is of a similar size and shape as existing Alcon phaco tips and is made with the same material (Titanium 6AL-4V alloy) as the Alcon phaco tips currently used on the INFINITI® System and CONSTELLATION® System. The ALCON® UltraChopper tip will utilize existing packaging configurations and have the same shelf life as existing phaco tips. It can be used with the same ultrasonic handpieces (INFINITI®, INFINITI® NeoSonix® or INFINITI® OZil) currently used on the Alcon systems such as the INFINITI® System and CONSTELLATION® System.

To use the ALCON® UltraChopper as intended, no modification to the existing INFINITI® System and CONSTELLATION® System software is required.

3. Indications for Use

The ALCON® UltraChopper is indicated to be used with an Ultrasonic Phacofragmentation Handpiece to separate a cataractous lens into smaller pieces.

4. Brief Summary of Non-clinical test and Results

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path have been performed to the following standards:

Standard #	Title
10993-1: 2003 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing
10993-5: 1999 AAMI/ANSI/ISO	Biological Evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
10993-10:2002/A1:2006 AAMI/ ANSI/ISO	Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and delayed-type hypersensitivity – Including A1:2006
10993-11:2006 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 11: Tests for systemic toxicity
10993-12:2007 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 12: Sample Preparation and Reference Materials

The ALCON® UltraChopper tip is provided sterile and intended for single use only. This product is Gamma sterilized and the process has been validated to a SAL of 10^{-6} per FDA Recognized Consensus Standard – "EN ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*".

Technological characteristics affecting clinical performance are similar to those of predicate devices previously listed. The ALCON® UltraChopper tip has been developed and will be manufactured in compliance with section 21 CFR 820 and ISO 14971:2003. Non-clinical testing has demonstrated that the functional requirements have been met and that the device is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Martin Kaufman
Director, Regulatory Affairs
Alcon Research, Ltd.
15800 Alton Parkway
Irvine CA 92618

OCT 20 2009

Re: K091777
Trade/Device Name: Alcon UltraChopper
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacoemulsification Tip
Regulatory Class: II
Product Code: HQC
Dated: September 25, 2009
Received: September 29, 2009

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

The Indications for Use statement is provided here and is also included in **Attachment A**. The ALCON® UltraChopper is intended for prescription use only.

510(k) Number (if known): k091777

Device Name: ALCON® UltraChopper

Indications for Use:

The ALCON® UltraChopper is indicated to be used with an Ultrasonic Phacofragmentation Handpiece to separate a cataractous lens into smaller pieces.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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